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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/727,423 | 12/04/2003 | Guilan Chen | 38-21(52232)C | 8132 |
| 27161 | 7590 | 05/03/2006 | EXAMINER | |
| MONSANTO COMPANY 800 N. LINDBERGH BLVD. ATTENTION: GAIL P. WUELLNER, IP PARALEGAL, (E2NA) ST. LOUIS, MO 63167 | | | KRUSE, DAVID H | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1638 | |

DATE MAILED: 05/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|-------------------------------|-----------------------------|--|
| Office Action Summary | Application No. 10/727,423 | Applicant(s) CHEN ET AL. | |
| | Examiner David H. Kruse | Art Unit 1638 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-3 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>4/30/2004</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Priority

1. It is noted that this application appears to claim subject matter disclosed in prior Application No. 09/682,597, filed 25 September 2001. A reference to the prior application must be inserted as the first sentence(s) of the specification of this application or in an application data sheet (37 CFR § 1.76), if applicant intends to rely on the filing date of the prior application under 35 U.S.C. § 119(e), 120, 121, or 365(c). See 37 CFR § 1.78(a). For benefit claims under 35 U.S.C. § 120, 121, or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of all nonprovisional applications. If the application is a utility or plant application filed under 35 U.S.C. § 111(a) on or after November 29, 2000, the specific reference to the prior application must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. § 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. § 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR § 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. § 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35

U.S.C. § 119(e), 120, 121 and 365(c). A benefit claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed benefit claim under 35 U.S.C. § 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. § 120 or 119(e) and 37 CFR § 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR § 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR § 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

If the reference to the prior application was previously submitted within the time period set forth in 37 CFR § 1.78(a), but not in the first sentence(s) of the specification or an application data sheet (ADS) as required by 37 CFR § 1.78(a) (e.g., if the reference was submitted in an oath or declaration or the application transmittal letter), and the information concerning the benefit claim was recognized by the Office as shown by its inclusion on the first filing receipt, the petition under 37 CFR § 1.78(a) and the surcharge under 37 CFR § 1.17(t) are not required. Applicant is still required to submit the reference in compliance with 37 CFR § 1.78(a) by filing an amendment to the first sentence(s) of the specification or an ADS. See MPEP § 201.11.

Claim Objections

2. Claim 1 is objected to because of the following informalities:

At line 5, "rise" appears to be a typographical error and should be -- rice --.

At steps 4 and 5 of the claimed method, the limitation "plants" is not in number agreement with "plant" at step 3. The Examiner suggests amending the claim to recite - a wheat plant or wheat plants --. It would be clear to one of skill in the art that the transformed wheat cell at step 2 could be used to produce a callus culture that could be used to produce one or more wheat plants.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

4. Claim 3 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim is indefinite because it is unclear if the progeny seeds comprise the DNA construct or if the claim encompasses non-transgenic seeds. Hence, the metes and bounds of the claim are unclear.

The claim is indefinite because the limitation "The progeny seeds" lacks proper antecedent basis in claim 2. The claim should read -- A seed of --.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

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the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. § 102(e), (f) or (g) prior art under 35 U.S.C. § 103(a).

7. Claims 1-3 are rejected under 35 U.S.C. § 103(a) as being obvious over Anderson *et al*, filed 15 September 2000 which claims benefit of US Provisional Application filed on 16 September 1999.

The applied reference has a common inventor and assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. § 102(e). This rejection under 35 U.S.C. § 103(a) might be overcome by: (1) a showing under 37 CFR § 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR § 1.131; or (3) an oath or declaration under 37 CFR § 1.130 stating that the application and reference are currently owned by the same party

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and that the inventor named in the application is the prior inventor under 35 U.S.C. § 104, together with a terminal disclaimer in accordance with 37 CFR § 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. § 103(c) as prior art in a rejection under 35 U.S.C. § 103(a). See MPEP § 706.02(I)(1) and § 706.02(I)(2).

Anderson *et al* teach plasmids pMON42411 and pMON30167 in the paragraph spanning columns 39-40. Applicant teaches that the claimed method uses a construct that combines said plasmids to produce a plasmid, pMON30139, having both expression cassettes previously taught by Anderson *et al* (see page 15 of the instant specification). Anderson *et al* teach that combining expression cassettes produces better glyphosate tolerance, both vegetative and fertility, in transgenic wheat plants (see column 42). It would have been *prima facie* obvious to one of ordinary skill in the art given the teachings of Anderson *et al* to combine the expression cassettes of plasmids pMON42411 and pMON30167 and transform wheat to make fertile glyphosate tolerant wheat. Given the success of Anderson *et al* to make transgenic wheat plants using a DNA construct comprising two expression cassettes having improved glyphosate tolerance, using pMON45362, one of ordinary skill in the art would have had a reasonable expectation of success in combining the expression cassettes of plasmids pMON42411 and pMON30167 and make glyphosate tolerant wheat plants.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. § 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Anderson *et al* disclose the expression cassettes used in the claimed invention, in addition to how to make and use DNA constructs comprising a first and a second expression cassette to make glyphosate tolerant wheat that is fertile as outlined above. Those of ordinary skill in the art would have had a reasonable expectation of success in combining the expression cassettes of plasmids pMON42411 and pMON30167 and transform wheat. Making and using DNA constructs having a first and a second expression cassette was well established in the instant art at the time of Applicants' invention.

8. Claims 1-3 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Zhou *et al* 1995 (Plant Cell Reports 15: 159-163) in view of Lundquist *et al* (US Patent 5,990,390) and Brown *et al*, 16 September 1999 (WO 99/46396).

Zhou *et al* teach transforming wheat with a DNA construct comprising a first and a second expression cassette to make a glyphosate wheat plant that is fertile (see page 162, left column).

Zhou *et al* does not teach transforming a wheat plant with a DNA construct comprising a first and a second expression cassette having the features as stated in Applicants' claim 1.

Lundquist *et al* teach a DNA construct having the components of the first expression cassette used in the method of Applicants' claim 1 in pDPG467 taught in Table 4 in column 64.

Brown *et al* teach a DNA construct having the components of the second expression cassette used in the method of Applicants' claim 1 in pMON19653 taught in Figure 6A.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the teachings of Zhou *et al* to make a glyphosate tolerant transgenic wheat plant using a DNA construct comprising said first and said second expression cassette as taught by Lundquist *et al* and Brown *et al*, respectively. Given the success of Zhou *et al* in making fertile glyphosate tolerant wheat plants transformed with a DNA construct comprising a first and a second expression cassette, one of ordinary skill in the art would have had a reasonable expectation of success. Both Lundquist *et al* and Brown *et al* teach making transgenic plants using a glyphosate tolerant EPSPS encoding DNA molecule to make said transgenic plants glyphosate tolerant.

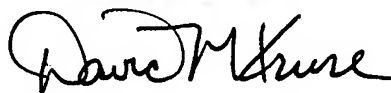
Conclusion

9. No claims are allowed.
10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (571) 272-0799. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached at (571) 272-0975. The fax telephone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (571) 272-0547.

DAVID H. KRUSE, PH.D.
PRIMARY EXAMINER



David H. Kruse, Ph.D.
20 April 2006

11. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

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